

***State of New York
Office of the State Comptroller
Division of Management Audit
and State Financial Services***

**DEPARTMENT OF AGRICULTURE
AND MARKETS**

FOOD SAFETY PROGRAM

REPORT 98-S-15



H. Carl McCall
Comptroller



State of New York Office of the State Comptroller

Division of Management Audit and State Financial Services

Report 98-S-15

Mr. Nathan Rudgers
Acting Commissioner
Department of Agriculture and Markets
1 Winners Circle
Albany, NY 12235

Dear Mr. Rudgers:

The following is our report on our audit of the Department of Agriculture and Markets' food safety program.

This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law. We list major contributors to this report in Appendix A.

*Office of the State Comptroller
Division of Management Audit
and State Financial Services*

June 7, 1999

Executive Summary

Department of Agriculture and Markets Food Safety Program

Scope of Audit

The Department of Agriculture and Markets' (Department) Division of Food Safety and Inspection (Division) is responsible for enforcing State laws and Department regulations related to food safety. The Division's objective is to ensure a safe and properly labeled food supply—from the producer to the retailer to the consumer. The Department works in conjunction with Federal agencies, other State agencies and local health departments to meet this objective. Division activities include: inspecting retail food establishments and food processors; analyzing food samples; seizing unfit or adulterated foods; issuing licenses to various types of food and feed establishments; investigating consumer complaints; carrying out enforcement activities; and providing food safety and labeling information to the industry.

Food safety is critically important in maintaining public health and in avoiding outbreaks of foodborne illness. Foodborne illnesses are generally caused by bacteria and other microorganisms in the food people eat.

Our audit of the Department's food safety program for the period January 1, 1996 through September 30, 1998 addressed the following questions:

- Does the Department take adequate steps to ensure food safety and to minimize the risk of foodborne illness?
- Does the Department measure the effectiveness of its food safety program?

Audit Observations and Conclusions

The Department needs to address a significant backlog in inspections to better ensure food safety and minimize the risk of foodborne illness. We recommend that Division officials continue to actively manage the food safety program and to pursue innovative options to increase the efficiency of the inspection process and reduce the backlog. We also found the Department does not measure this program's effectiveness, and recommend that it develop a performance measurement system to report program results to both Department management and to the public.

The Division is responsible for food safety inspections at more than 28,000 establishments. The Division has categorized establishments into six types according to the level of risk that any existing food safety deficiencies would pose to public health, and has set different inspection frequencies by establishment type. Division inspection records show that, as of June 1, 1998, there were 9,227 establishments—about one-third of

the total number—which had not been inspected according to the required frequency; the Division was also delinquent in reinspecting establishments which had failed inspections. Division inspection staff has decreased from 102 in fiscal year 1980-81 to 63 in 1996-97. Division officials indicated that staffing was increased to 75 inspectors subsequent to our audit.

Given the existing backlog in inspections, and the importance of this function in ensuring the safety of the State's food supply, we recommend the Division consider different strategies to manage its inspection workload. For example, we encourage the Division to continue to evaluate how emerging technology can improve efficiency and to consider centralizing the inspection process sooner than planned. We also suggest that the Division consider other management changes to reduce or eliminate the backlog and ensure that all establishments do not go extended periods without some Division oversight. For example, the Department could conduct more "blitz" inspections which focus on problem areas such as imported foods; develop incentives, such as an award program, for establishments with good quality control; and establish standard performance expectations for inspections. (See pp. 7-12)

The Department has not developed a comprehensive performance measurement system for its food safety program. By developing performance standards, measuring program accomplishments against the standards and reporting the results, the Department can improve accountability for its food safety program. Such information will also help management gauge the real impact of policy or process changes, such as those contained in this report. Although Division officials state that there is a very low incidence of foodborne illness associated with establishments under its jurisdiction, they have not established this measurement as a formal performance standard. We recommend the Department develop measurable performance standards for assessing its food safety activities. (See pp. 13-15)

Comments of Department Officials

Department officials state they are widely recognized as operating a model food safety program and that most of our recommendations are initiatives that the Department has already implemented.

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Major Contributors to This Report

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Comments of Department Officials

Introduction

Background

The overall mission of the Department of Agriculture and Markets (Department) is to foster a competitive food and agriculture industry to benefit producers and consumers. The Department's Division of Food Safety and Inspection (Division) is responsible for enforcing State laws and Department regulations related to food safety, which is a critically important factor in maintaining the health and well-being of the people of New York State. In the 1996-97 fiscal year, the Division employed 105 people, including 63 food safety inspectors, and had a \$6.3 million budget. The Division also has Farm Products Inspection staff and Food Safety office staff who are also involved in some food safety-related activities.

The Division's intent is to ensure a safe and properly labeled food supply—from the producer to the retailer to the consumer (“farm-to-fork”)—by:

- performing unannounced sanitary inspections of food manufacturers, wholesale bakeries, beverage processors, food warehouses, refrigerated warehouses, retail food stores (supermarkets to small grocery stores), slaughterhouses, fish processors, rendering/disposal plants, and food transportation services;
 - sampling food products for analysis by the Department's food laboratory;
 - providing information seminars for the food industry on food safety and labeling;
 - investigating consumer complaints;
 - licensing food operators of various types of establishments;
 - consulting with owners of food establishments and industry groups;
 - seizing unfit or adulterated foods;
 - ensuring proper food labeling and advertising; and
 - carrying out enforcement activities, such as imposing civil penalties or revoking licenses.
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The Department fosters cooperative working relationships with other food safety agencies and organizations, such as the State Department of Health (DOH) and local health departments, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the Central Atlantic States Association of Food and Drug Officials, the Association of Food and Drug Officials, the New York State Department of Environmental Conservation (DEC), and the U.S. Environmental Protection Agency (EPA).

Food inspection responsibilities are fragmented among various Federal, State and local government agencies. It is important that the various entities work cooperatively toward a common goal of ensuring food safety. In New York State, no single State agency has authority over the entire food inspection process. For example, while the Department is responsible for inspections at markets and processing facilities, DOH oversees restaurant inspections, many of which are performed by local health departments. Inspections of seafood and shellfish are performed by DEC. The Department has agreements with DOH and DEC which note the rights and responsibilities of each State agency with respect to food safety. The Department has responsibility for inspecting retail food establishments whose operations have less than 50 percent of their total annual receipts from food service sales (i.e., the sale of food that is consumed on the premises or of ready-to-eat food that is consumed off the premises). DOH or local health departments are responsible for inspecting establishments whose operations have 50 percent or more of their total annual receipts from food service sales.

Foodborne illnesses are generally those caused by microorganisms (also known as bacteria or pathogens) consumed by eating any type of food. Their effects can range from relatively minor discomfort to more serious problems, such as fever, diarrhea and dehydration, or even death. The International Food Information Council has identified five basic categories of foodborne illness agents, as listed below:

- Bacteria - Harmful bacteria account for more than two-thirds of all outbreaks of foodborne illness in the United States for which causes have been identified. Bacterial illnesses are usually characterized by diarrhea, fever and abdominal cramps. Of the thousands of different strains that can result in illnesses, four types cause most of the reported cases: campylobacter (can be found on raw or undercooked poultry or in unpasteurized milk); salmonella (can be found on various foods, including poultry, meat, eggs and unpasteurized milk); shigella (passed by infected food handlers who forget to wash their hands with soap after using the bath-

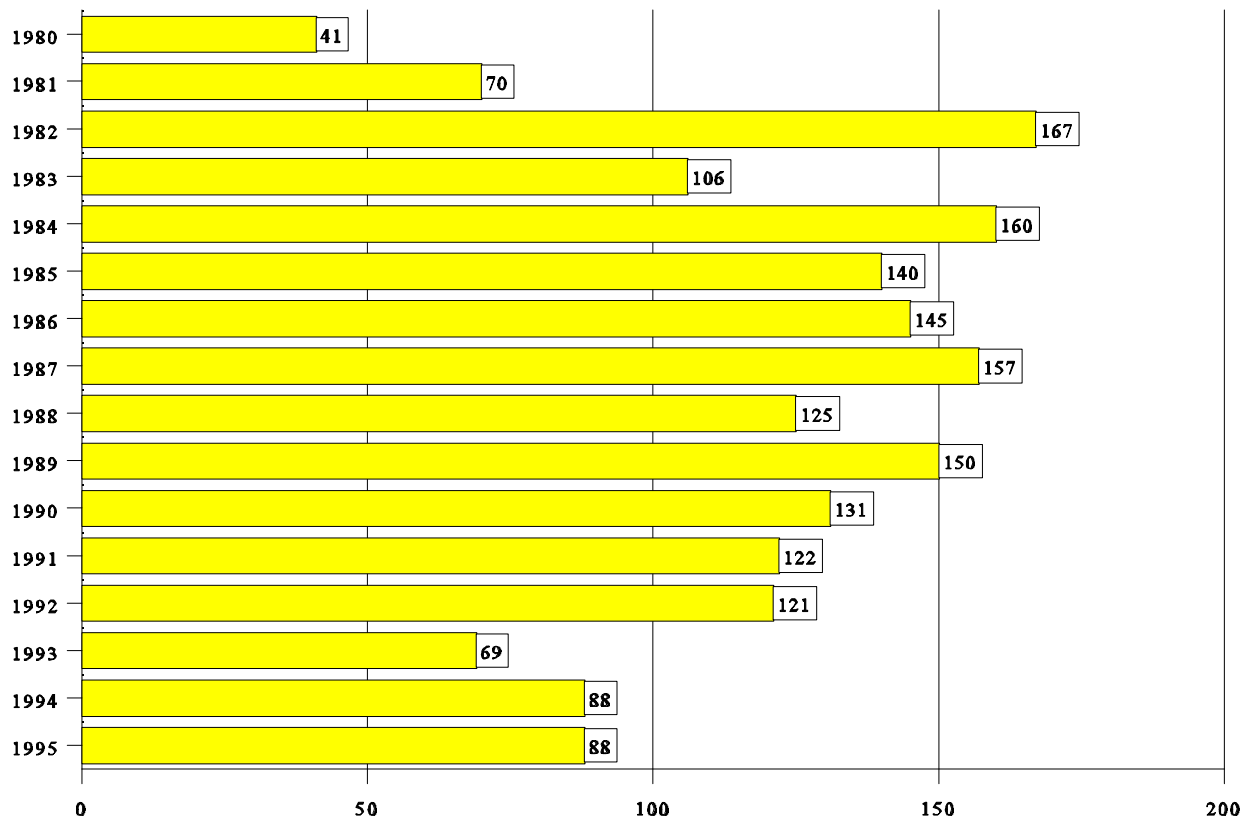
room); and E. coli 157:H7 (can be found on a number of different foods, primarily undercooked ground beef).

- Viruses - Viruses found in untreated water and in human feces can be a source of foodborne disease.
- Parasites - Food and water can carry parasites, such as tapeworms, roundworms and certain species of protozoa.
- Food toxins - Microorganisms can produce toxins in food stored at improper temperatures.
- Unknown - The cause of a great many foodborne illnesses are classified as “unknown” because no laboratory analysis is conducted to verify the specific cause.

Government officials and health experts consistently rate foodborne illnesses as the greatest food safety threat. They note that the magnitude of the problems posed by foodborne illnesses is difficult to measure; the incidences of such illnesses are likely underreported, and health officials often cannot determine the causes of cases that are reported. However, in May 1996, the U.S. General Accounting Office (GAO) reported that up to 81 million cases of foodborne illnesses—and as many as 9,100 deaths associated with those illnesses—are estimated to occur each year in the United States. Further, the USDA’s Economic Research Service reported that, in 1996, the estimated annual cost of medical treatments and productivity losses associated with these illnesses ranged from \$6.6 billion to \$37.1 billion.

In New York State, DOH reports there were nearly 1,900 outbreaks of foodborne illness between 1980 and 1995 (the latest year for which data was available at the time of our audit). During these outbreaks, a total of nearly 41,000 people became ill; 1,393 of them were hospitalized, and 35 died. As shown in the table below, the number of outbreaks ranged from a low of 41 in 1980 to a high of 167 in 1982. There were 88 outbreaks in 1995.

Outbreaks of Foodborne Illness in New York State -- 1980 to 1995



DOH reported it had identified causes for about half the total outbreaks reported. For each outbreak, there may be one or more causes, or factors that contributed to its occurrence. Some of the most commonly noted causes include: contaminated ingredients, the consumption of raw food, an unapproved source (such as imported food which does not meet U.S. inspection requirements), inadequate refrigeration, an infected person, and inadequate cooking. Division officials add that the percentage of foodborne illness outbreaks associated with establishments under its jurisdiction averaged less than 2 percent of the total for the 15-year period.

Audit Scope, Objectives and Methodology

We audited the Department's food safety program for the period of January 1, 1996 through September 30, 1998. The objectives of our performance audit were to determine whether the Department takes adequate steps to ensure food safety and to minimize the risk of foodborne illness, and to ascertain whether the Department measures the effectiveness of its food safety program. To accomplish our objectives, we interviewed Department officials, examined Department inspection records, reviewed

industry and government publications related to food safety, accompanied Division personnel on food safety inspections, and analyzed statistical information. We also contacted officials at Federal food safety agencies and at such agencies in other states.

We conducted our audit in accordance with generally accepted government auditing standards. Such standards require that we plan and perform our audit to adequately assess those operations of the Department which are included within the audit scope. Further, these standards require that we understand the Department's internal control structure and compliance with those laws, rules and regulations that are relevant to the operations which are included in our audit scope. An audit includes examining, on a test basis, evidence supporting transactions recorded in the accounting and operating records and applying such other auditing procedures as we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments, and decisions made by management. We believe that our audit provides a reasonable basis for our findings, conclusions and recommendations.

We use a risk-based approach to select activities for audit. We therefore focus our audit efforts on those activities we have identified through a preliminary survey as having the greatest probability for needing improvement. Consequently, by design, we use finite audit resources to identify where and how improvements can be made. We devote little audit effort to reviewing operations that may be relatively efficient or effective. As a result, we prepare our audit reports on an "exception basis." This report, therefore, highlights those areas needing improvement and does not address activities that may be functioning properly.

Response of Department Officials to Audit

A draft copy of this report was provided to Department officials for their review and comment. Their comments have been considered in preparing this report and are included as Appendix B.

Within 90 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Agriculture and Markets shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.

Inspecting Food Establishments

The Division is responsible for food safety inspections at more than 28,000 establishments. In 1983, the Division designated six categories of establishments based on "Indicators of Potential Hazard" (IPH), which classify the level of risk that any existing food safety deficiencies would pose to public health. The Division set different inspection frequencies by IPH type, ranging from three times per year to once every two years. If an establishment does not pass inspection, it must be reinspected between 30 and 90 days from the date of the initial inspection and show it has corrected the deficiencies. The following table shows examples of establishments in each IPH category, the scheduled inspection/reinspection frequency, and the number of establishments in each category.

Department of Agriculture and Markets Explanation of Indicators of Potential Hazard (IPH) Types				
IPH Type	Example of Establishments	Scheduled Inspection Frequency	Reinspection Frequency (1)	Number of Establishments
Type I	Food processors and manufacturers that have great potential health impact	Three times per year	30 days	161
Type II	Large retail food establishments such as supermarkets that have significant potential health impact	Two times per year	30 days	523
Type III	Non-licensed grocery stores and delicatessens handling exposed food as well as large food warehouses that pose moderate potential health hazards (2)	One time per year	60 days	22,791
Type IV	Lower volume warehouses and grocery stores not handling exposed foods	One time every two years	90 days	3,648
Type V	Poultry and small animal slaughterhouses and disposal plants	One time per year	60 days	923
Type VI	Small-scale food processors which pose little or no threat to public health	On a complaint basis	90 days	n/a
			Total	<u>28,046</u>
Notes: (1) If establishments do not pass inspections, they are subject to limited reinspections at intervals of between 30 and 90 days. (2) Department officials report that about 10,000 IPH Type III establishments have been treated as IPH Type IV establishments since 1996. However, they cannot be formally changed until the establishment is inspected and an Operational Change Report is submitted.				

We asked Division officials to identify their inspection backlog. From their computerized database as of June 1, 1998, Division officials prepared

a report for us which showed those establishments which were late in having an inspection according to the frequency established for the IPH categories. This report showed there were 9,227 establishments which were not inspected on time, representing nearly one-third of the Division's total inspection workload. We also found that some reinspections had not been completed on time. Division procedures require that inspectors must complete another full inspection of an establishment if the reinspection is not done timely. The following table shows the Division's inspection and reinspection backlog by type of establishment, as of June 1, 1998.

Department of Agriculture and Markets Analysis of Inspection Backlog and Reinspections Not Made Timely As of June 1, 1998				
IPH Type	Number of Establishments	Number of Establishments Not Inspected According to Schedule	Percentage of Establishments Not Inspected (in IPH Type)	Number of Establishments Not Reinspected According to Schedule
Type I	161	4	2.48%	3
Type II	523	75	14.34%	4
Type III	22,791	7,738	33.95%	350
Type IV	3,648	1,403	38.46%	7
Type V	923	7	0.76%	4
Type VI	n/a	n/a	n/a	1
Total	28,046	9,227	32.90%	369
<u>Note:</u> Department officials report that about 10,000 IPH Type III establishments have been treated as IPH Type IV establishments since 1996. However, they cannot be formally changed until the establishment is inspected and an Operational Change Report is submitted.				

The backlog of food safety inspections is attributable in part to the fact that the Division employs fewer inspectors now than it did 16 years ago to inspect about the same number of establishments. The Division reported that its inspection staff dropped from 102 inspectors in fiscal year 1980-81 to 63 inspectors in fiscal year 1996-97. During this period, the number of inspections performed also dropped—from 36,773 in 1980-81 to 17,918 in 1996-97. (This information does not include reinspections of establishments that failed inspections.) The decrease in the numbers of inspectors and inspections was accompanied by an increase in the number of violations (inspection failures) that occurred: from 14 percent of the establishments inspected in 1980-81 to 36 percent of those establishments

in 1996-97. This pattern raises questions about the impact of staff reductions on inspection activities.

Our prior audit of the Division (Report 91-S-32, issued June 24, 1991) found the Division was not making all its required inspections due to a lack of inspection staff and a high turnover rate in its downstate staff. Our current audit found the Division is still not making all the required inspections. In fact, the Division's delay in reinspecting establishments cited for critical deficiencies (defined as posing an "immediate" threat to public health), along with the long period of time the Division allows for the correction of deficiencies, means that establishments that failed inspections may be continuing in operation for extended periods. Division officials explain that most failing inspections represent a situation where product adulteration could occur, but is not imminent. Where product adulteration has occurred, the product is immediately seized and a temporary restraining order is sought if necessary.

Subsequent to our audit, Division officials informed us that staffing has been increased to 75 inspectors. While this should help reduce the backlog, we question whether the Division, faced with such a significant backlog in inspections and reinspections, can meet its own inspection schedule, even with the 12 additional inspectors. The Division needs to evaluate the adequacy of its staffing on an ongoing basis. In view of the importance of meeting the Division's food safety objective, we are recommending that the Division identify additional cost-effective methods for reducing the inspection backlog. We believe there are a number of options which the Division could emphasize and/or pursue to do this. In the remainder of this section, we identify some options which may help the Division manage and reduce the inspection backlog.

Technology

Using modern technology can improve efficiency and help achieve program results in an economical manner. The Division has evaluated how computer technology could improve the efficiency of its inspection staff and is in the process of equipping its inspectors with notebook computers so they can record inspection results and input the results to the Division's database. Division officials anticipate an increase in productivity as more inspectors use the notebook computers in the inspection process. In response to our draft report, Department officials indicated that in addition to the use of laptop computers, they have purchased and are assessing the use of point and read infrared thermometers and digital cameras. We encourage the Division to continue pursuing emerging technology.

Inspection Blitzes

The Division could also use its information database to identify establishments, geographic areas and/or types of food which have had a history of sanitary and food safety problems. Division officials concede that there are a few food safety issues which may not have been addressed effectively, such as imported food and food establishments operated by people from other cultures whose food-handling practices may compromise food safety. The Division has developed a task force with the FDA to inspect major importers in New York City for violations. The task force conducts investigations and samples products during “blitz” inspections, and it participates in any resulting legal actions. The Division may also be able to make more effective use of its inspection resources by conducting more “blitz” inspections of specific food products. It could also consider inspecting problem establishments more frequently and good establishments less frequently, and conducting focused inspections for specific sanitary violations or health-related issues. Division officials state that they make special assignments to address special problems as they arise.

Quality Assurance Programs

The Division should also review what the food establishments are doing on their own to prevent food contamination. Chain supermarkets, food processing plants and large bakeries may pose a unique opportunity for the Division to develop incentives for establishments with good quality controls. To the extent that these establishments have a central internal quality assurance function to ensure food safety, the Division could evaluate the effectiveness of the establishment’s quality assurance program. To induce such stores to develop and/or maintain good quality assurance programs, the Department should consider incentives such as an award program identifying good programs. The display of a “good quality assurance program” award from the State could help these stores advertise their dedication to good food quality.

Inspection Scheduling Process

Currently, the Division delegates inspection scheduling to its individual inspectors. The inspectors, who are assigned to certain geographic locations, generally work out of their homes and come to Division offices as needed. Division officials agree that centralized scheduling would be more efficient; however, they stated that central office or the senior inspector will probably begin scheduling inspections only when notebook computers have been distributed to all inspectors statewide—or in about two to three years. Considering the size and nature of the inspection backlog, the Division should move to centrally schedule food safety inspections as soon as possible, giving emphasis to reducing the inspection backlog.

We found that, depending on the type of establishment, an inspector can do from one to four inspections each day. However, the Division has not established performance standards related to how long inspections should take or how many establishments an inspector is expected to visit each week. Division officials stated that inspection time can vary widely depending on the complexity and size of the establishment; to apply average times for each type of inspection would be arbitrary and unrealistic. They added that supervisors are generally aware of average inspection times, and they review instances where actual inspection times are outside of a normal range so they can identify and deal with productivity problems. However, to appropriately manage its workforce and to reduce the inspection backlog, the Division needs to develop standardized performance expectations that state the length of time for inspections and the number of inspections to be completed; these standards could be based on ranges and should be flexible enough to acknowledge the complexity of inspections and size of the establishment being inspected.

Recommendation

1. Consider different strategies to increase the efficiency of the inspection process and reduce the inspection backlog, such as, but not limited to:
 - continually assessing the use of emerging technology in improving efficiency;
 - evaluating periodically the adequacy of staffing;
 - conducting more “blitz” inspections which focus on problem areas, such as imported foods;
 - considering incentives such as an award program for food establishments that have demonstrated good food quality control;
 - accelerating the Division’s plans to centralize the inspection scheduling process; and
 - establishing standard performance expectations for inspections.

Performance Standards

Governmental agencies are accountable for the effective, efficient and economical use of publicly-funded resources provided to accomplish their missions. Agencies can improve accountability over the programs they run by developing performance measures and performance standards, by assessing the success of the programs they administer, and by reporting the results to the public, to executive management and to elected officials. A performance measurement system is also a tool management can use to gauge the real impact of policy or process changes. In the Division's case, such changes could range from its distribution of laptop computers, to the results of its implementation of the recommendations contained in this report.

To measure performance, an agency must establish goals and objectives that are measurable and that relate to its mission, and develop meaningful performance indicators. A performance indicator is a particular value or characteristic which measures outputs (amounts of services or actions taken) or outcomes (results) which are indicative of progress toward the goals and objectives. We found that, while the Division does track certain data (such as the number of inspections performed, the number of violations per inspection, the effectiveness of the type of legal action taken, and the frequency of inspections required under the IPH ratings), it has not set specific goals against which management can measure actual performance—or the output and outcomes achieved—in these areas. The Division has set specific goals for the frequency of inspections, and does measure performance against these goals. Division officials state that, while historical data suggest a general correlation between inspection frequency and violation rate, there are many factors affecting performance which are beyond the Division's control. They do not believe establishing arbitrary goals and objectives will improve effectiveness. We agree, and stress that by setting relevant goals and objectives and measuring performance, the Division could improve the efficiency of its food safety program.

A public accountability reporting system should measure both outputs and outcomes. Output measures could include the number of food safety inspections, the average number of inspections per inspector, the time to complete inspections, and the average number of deficiencies cited in inspection reports. Outcome measures could include a reduction in the inspection backlog, or a reduction in the average number of critical deficiencies at establishments, by a specific amount each year.

The Division's mission, as it relates to food safety, is ensuring a safe and properly labeled food supply. This mission may not be specific enough to provide goals and objectives that serve as criteria in developing performance measures. Further, the Division cannot substantiate the extent to which its activities are accomplishing this broad mission. While Department officials agree that the number of foodborne illnesses would be a good performance indicator, it is difficult to obtain up-to-date and accurate information about the incidence of these illnesses because: foodborne illnesses are difficult to trace to a source and are often unreported; the causes of foodborne illnesses are not under the Division's direct control, since consumers and other regulatory agencies share responsibilities for food safety; foodborne illness data from DOH is more than two years old; and reporting comparisons with other states may not be feasible, since other states may accumulate and report foodborne illness data in different ways. Division officials do report, however, that the number of foodborne illnesses attributed to establishments under its jurisdiction is consistently low.

However, it is certainly possible to develop other meaningful performance measures related to food safety. Other states, such as Florida and Texas, have developed both output and outcome performance measures. For example, Florida has set a goal of reducing the incidence of "poor" inspection findings at food establishments from 6.8 percent to 6.5 percent by July 1, 2001. Florida has also established an output measure that involves increasing by 20 percent the number of food samples analyzed to identify exceptions to food safety and/or fraudulent labeling practices by July 1, 1999. Texas has established specific performance measures for each of its regions, including the number of inspections and the number of enforcement actions taken. Texas also uses an efficiency measurement of "average inspection time to available work time"; the target percentage of average inspection time to available work time was set at 48 percent for one of its regions. We believe the Division could use the experiences of other states as a starting point in developing its own performance measurement system. However, Division officials argued that setting arbitrary goals would have little impact on making progress on major program efforts, such as productivity and violation rates.

Recommendation

2. Develop appropriate program goals and objectives related to the Division's mission to ensure a safe and properly labeled food supply in New York State, and develop meaningful ways to measure outputs and outcomes. Consider the measurements used by other States as benchmarks to piloting a performance measurement system.

Major Contributors to This Report

Frank J. Houston
Dominick Vanacore
Roger C. Mazula
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January 29, 1999

Mr. Frank Houston
Audit Director
Office of the State Comptroller
Division of Management Audit
270 Broadway, 19th floor
New York, NY 10007

Dear Mr. Houston:

Attached is the Department's response to the Comptroller's audit of the Department's Food Safety Program.

The Department is very concerned over report recommendations that, if implemented, pose a threat to public health. The most serious example is the recommendation to reduce the frequency for inspecting certain high risk food processing establishments. Since this is a food safety issue we believe such decisions should be made by people trained in food sanitation matters.

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Note
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It is disconcerting that while New York State is widely recognized as having one of the most effective food safety programs in the country no mention of such is presented in the Executive Summary. While several positive statements to this effect are scattered throughout the report, the significance is lost. The fact that a high ranking FDA official stated New York is one of four states that does as good or better a job in the area of food safety as they do speaks volumes to the high esteem with which our program is held. The Department was one of six states selected nationally to participate in the Pesticide Data Program based on the high quality of our food inspection and laboratory testing program. Our Food Safety Division's Assistant Director was elected by his peers in other states to serve as President of the Association of Food and Drug Officials. This recognition is well deserved as evidenced by the low incidence of food borne illnesses attributable to establishments under our jurisdiction. These facts all warrant inclusion in the Executive Summary so as to present an accurate and unbiased portrayal of our food safety program.

Finally, we are concerned with the extent and manner in which the report takes credit for Department initiatives. For example, the Department began a project to automate the field

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*See State Comptroller's Notes

Appendix B

inspection and reporting process in 1995, yet the report provides no mention of its success and instead recommends assessing the use of modern technology to improve efficiency. The report also recommends reassessing the frequency of inspections despite the Department having done so prior to the start of the audit.

We hope that you will reevaluate your conclusions and recommendations and present a fair and accurate portrayal of our food safety program. If you have any questions regarding our response, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "L. J. Emminger", with a long horizontal flourish extending to the right.

Lawrence J. Emminger, CFE, CGFM
Director of Internal Audit

attachment

DEPARTMENT OF AGRICULTURE AND MARKETS
RESPONSE TO FOOD SAFETY AUDIT (#98-S-15)

Transmittal Letter

The Commissioner's name is spelled Davidsen.

Executive Summary

No mention is made in the Executive Summary of the Department's reputation with USDA, FDA and other states regarding the high quality of its food safety activities. While mentioned casually in the body of the report, the high marks given the Department by the agencies that establish the benchmarks for food safety programs should be included in the Executive Summary. Also, based on your audit research and discussions and correspondence with federal and other state officials it should be clear that the Department is widely recognized as operating a model food safety program. As you are aware, the Department was one of six states selected by USDA to participate in the Pesticide Data Program (PDP) based on the high quality of its inspection program and testing laboratory. A high level official in FDA's Center for Food Safety and Applied Nutrition recently stated that she considered New York to be one of four states which did as good or better a job in the area of food safety than FDA. Another indicator of the high esteem in which our food safety program is held is the Division's Assistant Director currently serving as President of the Association of Food and Drug Officials, a national organization comprised of various State and Federal officials with food safety responsibilities.

Department efforts to address inspection backlogs were initiated well before the audit was started. Since early 1995, the Governor has demonstrated

his commitment to a strong food safety program in New York State. Staffing is now back up to 75 inspectors and a major technological program was initiated in 1995 to computerize the field inspection and reporting process. As a result of these efforts, the Division of Food Safety is on track to conduct at least 31,000 inspections during the 1998-99 fiscal year, a level last achieved during 1984-85.

While there are several noteworthy recommendations in the Executive Summary, there is no mention that they are merely a reaffirmation of Department efforts initiated prior to commencement of the audit. To claim them as your own is at best a disservice to Division of Food Safety management.

It is a misstatement of fact to say that the Department has not developed a comprehensive performance measurement system for its food safety program. Just because another state uses different measures it does not mean that the ones we use are not effective in demonstrating program effectiveness. What better measurement is there than the low incidence of food borne illnesses traceable to establishments under our jurisdiction?

Background

The statement that the Division employed 105 people, including 63 food safety inspectors and had a \$6.3 million budget is incorrect since it does not include the Division's Farm Products Inspection staff and Food Safety office staff. This brings the Division total to approximately 175 full-time employees plus an additional 50-60 seasonal farm products inspectors. It should be noted that our Farm Products Inspection unit is involved in some food safety related activities; i.e. USDA Pesticide Data Program sampling, custom slaughter inspections and egg pasteurization plant inspections.

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Note
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The statement that the Division "prefers to work with establishments to correct conditions which might lead to foodborne illness rather than fine them for violating food safety standards" suggests that we put the industry's concerns

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above our legal mandate to insure a safe food supply. This is clearly not the case. We utilize all of the legal tools at our disposal including warning letters, industry conferences, civil penalties (\$2,318,950 in calendar year 1998), administrative hearings, seizures, injunctions, temporary restraining orders, contempt of court proceedings, summary suspensions of licenses and arrest warrants, to obtain compliance. There is no basis for equating the use of warning letters and industry conferences with being soft on industry to the detriment of the consuming public. Interestingly, 43% of establishments which were monetarily penalized following a first failing inspection passed the next inspection while 56% of those who received a warning letter following a first failing inspection passed the next inspection. Industry compliance conferences have also been very effective in gaining compliance with approximately 70% of those establishments attending a conference passing their next inspection.

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Note
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Inspecting Food Establishments

The Division of Food Safety and Inspection has taken positive steps to address the backlog in inspecting food establishments. This problem originated with the prior administration when repeated staff cutbacks reduced our inspection force to an all time low of 62. This trend has since been reversed. Staffing is now back up to 75 inspectors and a major technological program was initiated in 1995 to computerize the field inspection and reporting process. As a result of these efforts, the Division is on track to perform approximately 31,000 to 32,000 inspections during the current fiscal year, a number last achieved during the 1984-85 fiscal year. As a result, we are steadily reducing the number of overdue inspections and reinspections.

The chart on Page 7 indicates that 22,791 establishments are categorized as having a Type III Indicator of Potential Hazard (IPH). This misrepresents the actual status of these establishments since about 10,000 IPH III's have been treated as IPH IV's since 1996 and, therefore, are not actually overdue for

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inspection or reinspection as the chart indicates. This was brought to the attention of the audit team who, for whatever reason, have omitted it from the report.

The revision of our computer files to account for this revision is underway. This process is, however, somewhat time consuming since it requires a visit to each establishment by an inspector who then submits an Operational Change Report (OCR) to formally change the establishment's classification.

The report indicates that 36,773 inspections were performed in FY1980-81 and 17,918 inspections were performed in FY1996-97. These numbers represent only those inspections which followed a passing inspection. Total inspections performed (inspections following passing inspections and reinspections following failing inspections) were 43,260 in FY1980-81 and 28,341 in FY1996-97. Preliminary inspection totals for calendar year 1998 indicate that we performed approximately 30,000 inspections, a significant increase over the 25,542 inspections performed in calendar year 1997 and as indicated above we anticipate FY1998-99 totals will be between 31,000 and 32,000 inspections, again a significant increase over the 26,676 inspections conducted in FY1997-98.

We would like to reiterate that the report's conclusion that an *establishment failing an inspection be closed at once because of an immediate threat to public health* is flawed since it does not take into account that there are varying degrees of hazard associated with critical deficiencies. Most failing inspections represent a situation where product adulteration could occur, but is not imminent. Others clearly represent an imminent threat of product contamination and an immediate corrective action is necessary. For this reason, our inspection report consists of both a checklist and narrative report. This facilitates the decision-making process by our Sanitation Compliance Unit which reviews all such reports and decides on a course of action. And now, thanks to

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our field computer system, the Compliance Unit has access to these reports within one day of their completion.

In those cases where product adulteration has occurred, product is seized on the spot by the food inspector and, where necessary, the Department petitions the court for a Temporary Restraining Order which, in effect, closes the establishment. The Department never walks away from a situation where food is being adulterated.

Use of Technology

The Division has made great strides in the utilization of modern technology in our inspection program and plans to continue to take advantage of new developments as they become available. For example, in addition to the use of laptop computers, we have purchased and are assessing the use of point and read infrared thermometers and digital cameras. The comments made in this section of the report take credit for what the Division is already doing.

Reassess Facilities to be Inspected

The conclusion that the Division needs to reevaluate IPH categories is based on faulty analysis since the Division had already re-evaluated its IPH ratings system and created a subtype for IPH III establishments long before the current audit took place. The audit team was aware of this change yet for some reason omitted it from the report. A memo was sent out to field staff in 1996 advising them that until further notice Type III establishments which met certain criteria would be inspected at the frequency established for IPH IV establishments. We believe this change has worked well and are in the process of altering our computer files to reflect the IPH IV status of a significant portion of those establishments currently categorized as IPH III establishments in our

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records. As mentioned previously, this is a somewhat time consuming process since each establishment needs to be inspected prior to formalizing a change in category.

Focus Inspections on Critical Deficiencies

The Division does in fact modify the scope of inspections when warranted. As you are aware, the Division has instituted a critical deficiency only inspection criteria for certain reinspections and consumer complaint inspections. These decisions are based on food sanitation issues, not simply as an arbitrary means to eliminate a backlog. We also believe that your recommendation to implement such a policy for all inspections would eliminate any incentive to comply with regulations which are now categorized as general deficiency violations.

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Conduct Inspection Blitzes

The current IPH rating system and reinspection schedule were designed to identify categories of establishments which require more attention and to direct resources to those problems. Our workload data and subsequent assignment of personnel is based on this information as well as establishment failure rates in specific zones and regions. We believe the current system does an excellent job of putting resources where the workload and problems are. In those instances where special problems have arisen (i.e. live poultry markets in New York City, imports and Chinatown), special assignments have been made to address the problem. Also, when we identify a problem which warrants the recall of an adulterated product (we instigated more than 100 such recalls last year, easily the highest of any state in the U.S.), we put as many inspectors as necessary on the project to get the job done as expeditiously as possible.

Evaluate Quality Assurance Programs

Because of the highly complex and hazardous processing operations currently conducted in large supermarkets, we believe that your recommendation to reduce the current level of regulatory oversight would pose a threat to public health. Establishments which have effective quality assurance programs and therefore a low failure rate are already inspected at a rate which is less than comparable establishments which fail inspections and are placed on an accelerated reinspection schedule.

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Modify Inspection Scheduling Process

As stated in discussions with members of the audit team the Division intended to centralize scheduling of inspections once our computerization project was complete.

The recommendation that the Division establish performance standards which would stipulate how long an inspection should take and how many inspections should be performed each week does not recognize the tremendous disparity between establishments. The time necessary to conduct an inspection of establishments with the same IPH rating can vary widely depending on the complexity and size of the establishment, the number of violative conditions, whether samples are picked up, whether a seizure is made, travel time between establishments, etc. Volume of other assignments such as consumer complaints and foodborne illness investigations also vary tremendously and impact on the number of inspections performed. Regrettably, all science, including food science, does not fit in standardized time or dollar boxes.

The Division is aware how long on average it takes to conduct an inspection of a typical IPH Type I, Type II, etc., but applying that rule to all

inspections and inspectors across the state would be arbitrary and unrealistic. The present system, which relies on oversight by field supervisors, as well as statistical data on regions, zones and individual inspectors to spot productivity problems, has proven to be very effective.

The Department does in fact periodically inspect establishments at odd hours and on weekends. This has been proven to be productive and we will continue to utilize this strategy in those situations when appropriate.

Recommendation

1. The recommendation does nothing more than take credit for many initiatives already undertaken by the Department. Credit should be given where it belongs - to the program staff for operating what is generally recognized as *one of the best food safety programs in the country.*

Performance Standards

There was no recommendation in the prior audit to develop comprehensive performance standards. The report merely said that the development of standards in this area was difficult. The Department did in fact have performance standards at that time and continues to have them.

As noted in the report, the Division of Food Safety and Inspection very carefully monitors statistical data in a number of ways. This information is utilized by Department and Division administrators as well as Division field supervisory staff to identify areas or individuals which may require attention. It includes areas such as violation rates, travel time and numbers of sanitary

inspections, seizures, samples, recalls, etc. This information is utilized to enhance training, reallocate resources and revise, as needed, inspection or compliance procedures and/or regulations.

In establishing goals and objectives our primary consideration is that such goals produce realistic targets that are not arbitrary in nature since so many factors affecting performance is beyond our control. While historical data suggests that there is a general correlation between inspection frequency and violation rate, it is not possible to predict, with any degree of specificity, the extent to which performing additional inspections impacts on the establishment failure rate. Our goal has always been to manage our resources in the best possible way so that the people of New York receive the kind of regulatory oversight of the food industry which they deserve. We do not believe establishing additional arbitrary goals and objectives will improve our effectiveness.

We firmly maintain that the percentage of foodborne illness attributed to establishments under our jurisdiction is an extremely relevant measure of program effectiveness and deserves more than a passing mention in the report. While recognizing that many cases of foodborne illness go unreported, such unreported data applies to foodborne illness cases across the board, regardless of source. The one statistical outcome which has remained constant throughout the years has been the extremely low number of foodborne illnesses attributed to establishments under our jurisdiction. This performance measurement's importance should not be discounted by the report.

The report's reference to goals established by Florida and Texas suggest these two states established goals but makes no reference to their success in attaining these goals or the impact on the effectiveness of their respective programs. It is also not clear whether the "performance measures" utilized by Texas constitute goals or simply means of assessing performance. As you are

aware, we also monitor percentage of "inspection time to available work time," as well as specific data pertaining to travel time and time spent on a variety of inspections, investigations, sampling and other activities, all of which are utilized as noted above as management tools. While establishing arbitrary goals in these areas might satisfy your recommendation of committing to very specific goals and objectives, it would, in reality, have little impact on our ongoing efforts to make the maximum possible progress in those areas of concern; i.e. productivity, violation rates, etc.

Recommendation

2. The Department already has performance standards for assessing Division activities.

Consumer Education

While not having clear statutory authority to conduct such activities, the Department routinely initiates and participates in a variety of consumer food safety efforts, including the issuance of press releases and the development and distribution of educational materials such as the "Safeguarding Your Food" publication. In addition, we have approached Cornell's Food Science Department about a joint initiative to develop a safe food education campaign.

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The following are additional examples of other Department initiatives in this area:

The Department, along with the USDA, the State Health Department and Cornell University, participated in a New York State Food Safety Education campaign which developed consumer education material aimed at encouraging consumer-safe handling and preparation of ground beef.

A similar education campaign developed jointly by this Department and the State Department of Health was successful in halting an outbreak of Yersiniosis among infants and toddlers in the Buffalo area resulting from the mishandling of chitterlings by consumers in that area.

As you are aware the New York State Health Department is the lead agency in the investigation of foodborne illness in New York State and any reports received by Agriculture and Markets are subsequently brought to their attention. Therefore, we believe it would be more appropriate for the public at large to continue to utilize established Health Department foodborne illness reporting procedures.

Recommendations

3. The Department already conducts consumer education programs as warranted.

4. The NYS Department of Health is the lead agency for the investigation of food borne illness in New York. Fragmenting responsibility for reporting illnesses would confuse consumers.

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State Comptroller's Notes

1. Certain matters addressed in the draft report were revised or deleted from the final report. Therefore, some agency comments included in Appendix B may relate to matters no longer contained in this report.
2. The Department's statement that, "the report's conclusions that an establishment failing an inspection be closed at once. . ." was not made in either the draft or final report.
3. The section in the draft report concerning Consumer Education and related Recommendations 3 and 4, were deleted from the final report.